Advancing the Development and Implementation of Analysis Data Standards: Key Challenges and Opportunities
Tommy Douglas Conference Center • Silver Spring, MD
June 12, 2019

Agenda

9:00 a.m. Welcome and Overview
  • Gregory Daniel, Duke-Robert J. Margolis, MD, Center for Health Policy

9:15 a.m. Opening Remarks
  • Laura Lee Johnson, U.S. Food & Drug Administration

9:30 a.m. Session I: FDA Efforts to Support Analysis Data Standards for Product Development and Review
  • Matilde Kam, U.S. Food & Drug Administration
  • Vaishali Popat, U.S. Food & Drug Administration

10:15 a.m. Break

10:30 a.m. Session II: Industry Experience with Data Standards During Product Development and Review
  Moderator: Gregory Daniel
  Presenters:
  • Patti Compton, Pfizer (PhRMA)
  • Stephen Hamburg, GlaxoSmithKline (PhRMA)
  • Ralph DeMasi, ViiV Healthcare
  Panel Discussants:
  • Brenda Baldwin, U.S. Food and Drug Administration
  • Michael Nessly, ICON
  • Peter Van Reusel, Clinical Data Interchange Standards Consortium
  • Lauren Shinaberry, AbbVie
  • Nhi Beasley, U.S. Food and Drug Administration

12:00 p.m. Lunch

1:00 p.m. Session III: Additional Applications and Impact of Data Standards on Clinical Research and Development Outside of Industry
  Moderator: Gregory Daniel
  Presenters:
  • Jose Galvez, National Institutes of Health
  • Jackson Burton, Critical Path Institute
  Panel Discussants:
  • Frank Rockhold, Duke University
  • Stephan Grupp, Children’s Hospital of Philadelphia
• Shaojun Zhu, University of California at Los Angeles (Society of Nuclear Medicine & Molecular Imaging)
• Eileen Navarro-Almario, U.S. Food & Drug Administration

2:00 p.m.  Break

2:15 p.m.  Session IV: Key Opportunities to Improve the Implementation of Analysis Data Standards  
Moderator: Matilde Kam  
Panel Discussants:
• Weiya Zhang, U.S. Food and Drug Administration  
• Yuki Ando, Pharmaceuticals and Medical Devices Agency, Japan  
• Jessica Hu, U.S. Food and Drug Administration  
• Russell Reeve, IQVIA  
• Christopher Price, Roche (PhUSE)

3:15 p.m.  Session V: Emerging Trends and Innovations for the Development and Use of Analysis Data Standards  
Moderator: Gregory Daniel  
Presenter: David Martin, U.S. Food and Drug Administration  
Panel Discussants:
• Scott Gordon, U.S. Food and Drug Administration  
• Tim Stoddard, Flatiron Health  
• Peter Van Reusel, Clinical Data Interchange Standards Consortium  
• Christopher Chute, Johns Hopkins University  
• Robert Califf, Duke University

4:30 p.m.  Closing Remarks and Adjournment

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